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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,454	09/24/2003	Timothy C. Gillette	103184-0002U	4595
24267	7590	12/15/2006	EXAMINER	
CESARI AND MCKENNA, LLP 88 BLACK FALCON AVENUE BOSTON, MA 02210			WATTS, ALLISON LEIGH	
			ART UNIT	PAPER NUMBER

1753

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,454

Applicant(s)

GILLETTE ET AL.

Examiner

Allison L. Watts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/24/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 16. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 58. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by

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the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

1. The disclosure is objected to because of the following informalities:
2. The phrase "Fig. 8" on page 5 should read "Figs. 8A and 8B".
3. The phrase "Figs. 8A and B" on page 10 should read "Figs. 8A and 8B".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Benton.

As to Claim 1, Benton discloses a multimode electrochemical sensing array comprising a semiconductor chip (56) (Column 5, lines 13-18) having formed thereon an ion-selective field effect transistor (ISFET) (54) with an exposed gate (60) for contact with a test medium when immersed therein, wherein the gate is surrounded by a conductive surface (144) that serves as an

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electrode and a light shield (Column 4, lines 22-30), and also formed on the chip is a plurality of electrodes (316) spaced remotely from the transistor, and connectable in circuit with said conductive surface and an external current source for determination of a parameter of the test medium (Figures 2A-2E, 6C, 7, and 9, Column 4, lines 9-50).

As to Claims 6 and 7, Benton discloses the sensing array with at least one remotely spaced electrode connectable through a potential regulating element comprising a varistor (306, 308) to the conductive surface limiting potential on the surface (Figure 9B, Column 7, lines 58-67).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. in view of Benton and Hsiung et al.

As to Claim 1:

Wolf et al. disclose a sensor (4) comprising a semi-conducting substrate (5) having formed thereon an ISFET (ion-selective field effect transistor) (11), which has an exposed gate (12) for contact with a sample (Figures 6-9, Column 7, line 63 through Column 8, line 2, Claim 5). Also formed on the substrate is a plurality of electrodes (19) spaced remotely from the transistor, at least one of the electrodes being connectable in circuit with the ISFET (Figure 11, Column 8, lines 45-60, Claims 1, 2, and 4), and with an external current source for determination of a parameter of the sample (Figures 12 and 13, Column 8, line 61 through Column 9, line 16).

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Wolf et al. do not disclose the gate of the transistor being surrounded by a conductive surface that serves as both an electrode and a light shield for the transistor.

Benton discloses an ISFET sensor assembly (52) in which a semi-conductive substrate (56) (Column 5, lines 13-18) comprises an ISFET with an exposed gate through aperture (146) for contact with a test solution (Column 6, lines 46-55), where the ISFET is covered by a thin layer of metal (144) that may be used as an electrode and a light shield (Figures 6C and 7) (Column 4, lines 9-30), and where the ISFET is electrically connected to substrate binding pads (70a-70c) (Column 6, lines 58-63).

Hsiung et al. disclose that shielding an ion sensitive field effect transistor can increase accuracy of measurement of the ion concentration (Column 2, lines 15-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor disclosed by Wolf et al. by providing a conductive surface that surrounds the ISFET as disclosed by Benton and Hsiung et al., because it is advantageous to protect the ISFET from light to allow for increased measurement accuracy, as well as to provide an additional electrode for fluid measurements.

As to Claims 6 and 7:

Wolf et al. do not disclose at least one of the remotely spaced electrodes connectable through a potential regulating element to the conductive surface for limiting the potential on the conductive surface.

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Benton discloses a sensor assembly in which a substrate (304) comprises an ISFET (302), metal oxide varistors (MOVs) (306 and 308), and conductive traces (316) (Figures 9A and 9B, Column 7, lines 58-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor disclosed by Wolf et al. by providing a potential regulating element that comprises a varistor as disclosed by Benton because varistors are helpful in protecting circuits against excessive voltages applied to them.

As to Claim 8:

Wolf et al. further disclose a control unit that allows an adjustment of the current and voltage for the sensors selectively and for the reference elements assigned to them (Column 8, line 61 through Column 9, line 16).

Wolf et al., Benton, and Hsiung et al. do not disclose a remotely spaced electrode connectable with ground to connect a test solution to ground potential.

Benton discloses using a thin layer of metal formed over the gate of the ISFET to provide an electrical ground to the solution (Column 4, lines 22-25).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor as disclosed by Wolf et al., Benton, and Hsiung et al. by connecting a remote electrode to ground as disclosed by Benton because any of the electrodes could be connected to various reference elements through the control unit disclosed.

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10. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al., Benton, and Hsiung et al., as applied to Claim 1, and further in view of Eddowes.

Wolf et al., Benton, and Hsiung et al. do not disclose the current source being polarized to provide a titrant in the vicinity of the gate or at least one remotely space electrode.

Eddowes discloses a system comprising an ISFET (22) and an ENFET (23) (enzyme-modified ion sensitive field effect transistor) on a semiconductor substrate, where a titrating electrode (29) may be associated with either the ISFET (Figure 5) or the ENFET (Figure 4) (Column 7, lines 6-34).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor disclosed by Wolf et al., Benton, and Hsiung et al. by providing a titrant in either the vicinity of the gate or a remotely spaced electrode as disclosed by Eddowes, because a titrating electrode in either case may be used to determine analyte concentration (Column 7, lines 30-34).

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al., Benton, and Hsiung et al., as applied to Claim 1, and further in view of Garshol et al.

Wolf et al. disclose providing electrodes (19) at both sides of the ISFET (11) and that further electrodes may be added adjacent to the sensors (4) (Figures 9 and 11, Column 8, lines 45-49 and 59-60), and arranging electrodes in pairs (Column 4, lines 5-8), and connecting the electrodes to an external current

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source and an external voltage meter to provide conductivity measurements of the sample (Figures 12 and 13, Column 8, line 61 through Column 9, line 16).

Wolf et al. do not disclose a first pair of remote electrodes and a second pair of remote electrodes, the second pair being of a smaller size than the first.

Garshol et al. disclose that the limiting current density increases as the size of an electrode decreases.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrodes of Wolf et al. by varying electrode size in order to control current density as disclosed by Garshol et al., because it would enable a limited current density across the surface of the electrode.

12. Claims 5 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al., Benton, and Hsiung et al., as applied to Claim 1, and further in view of Matsumoto.

As to Claim 5:

Wolf et al. further disclose the substrate (5) including additional ISFETs to serve as reference elements or sensors (20), separate from the ISFETs designated for contact with a the test sample, to enable compensation of the temperature drift and the offset voltage of the sensors (Figure 11, Column 8, lines 53-68), as well as two AgCl reference electrodes (35) (Figure 13, Column 9, lines 14-16).

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Wolf et al., Benton, and Hsiung et al. do not disclose a remotely spaced electrode for performing oxidation/reduction measurements with respect to an external reference electrode.

Matsumoto discloses a sensor that includes an ion selective field effect transistor (57) and other remotely spaced electrodes (7, 8, 9) positioned on a substrate (Figure 30, Column 29, lines 33-46), as well as using an electrode to measure glucose concentration along with an external reference electrode, where the reference electrode is soaked in a measured solution for measurement purposes in an electrode system (Column 19, lines 44-56).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor disclosed by Wolf et al., Benton, and Hsiung et al. by using a remote electrode for measuring a reaction along with an external reference electrode as disclosed by Matsumoto, because an electrode may be used for many types of reaction measurements, including oxidation/reduction measurements, which signify intended use of the electrodes, and an external reference electrode is essential when performing electrode measurements to provide a stable and well-known electrode potential.

As to Claim 9:

Wolf et al. disclose a control unit that allows an adjustment of the current and voltage for the sensors selectively and for the reference elements assigned to them (Column 8, line 61 through Column 9, line 16).

Wolf et al., Benton, and Hsiung et al. do not disclose at least one electrode connectable in circuit with an external source of constant current.

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Matsumoto discloses applying a constant potential to a biosensor in order to determine a current value (Column 26, lines 55-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor disclosed by Wolf et al., Benton, and Hsiung et al. by applying a constant current as disclosed by Matsumoto because the control unit may be used to supply any desired current value, and a constant current can be useful for gathering measurements.

As to Claims 10 and 11:

Wolf et al., Benton, and Hsiung et al. do not disclose at least one electrode connectable in circuit with an external source of current that increases linearly over a range.

Matsumoto further discloses that relative outputs being linear for a sensor enables measurement of higher concentrations of an analyte (Column 33, lines 39-46).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor disclosed by Wolf et al., Benton, and Hsiung et al. by connecting an electrode with a current that increases linearly as disclosed by Matsumoto because it would allow for measurement of higher concentrations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison L. Watts whose telephone number is

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(571) 272-6640. The examiner can normally be reached on Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALW
12/7/06



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